Representing, Educating and Promoting the Restaurant/Hospitality Industry

1200 SEVENTEENTH STREET NW, WASHINGTON DC 20036-3097 202/331-5900 FAX: 202/973-3952

NATIONAL RESTAURANT ASSOCIATION

April 4, 2003

1704 '03 APR -4 P3:45

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276

Dear Sir or Madam:

Founded in 1919, the National Restaurant Association is the leading trade association for the restaurant industry. Representing more than 60,000 members and over 300,000 restaurant outlets in 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands, the National Restaurant Association has always supported government security enhancement of the nation's food supply. The restaurant industry has invested billions of dollars in the last two years to improve food security and food safety. Our efforts have clearly made a difference in protecting our nation's food supply.

We have a direct and vested interest in the proposed rules regarding the Registration of Food Facilities which were released in February 2003 and wish to submit formal written comments for the record concerning Docket No. 02N-0276, Federal Registrar, Volume 68, Number 22, February 03, 2003, pages 5377-5428. We appreciate the opportunity to comment on the newly released FDA registration guidance and are pleased that the Agency has requested input from the restaurant industry and others regarding their food security recommendations for the food industry from farm-to-table.

The restaurant industry has a long standing commitment to food safety and food security to protect our customers and our industry. The safety and security of the food supply, our customers and our employees is our top priority, and has been underscored by the September 11th attacks. We fully support the need and intent of the 2002 Bioterrorism Act, and we commend the Agency for attempting the very difficult task of developing registration guidelines for the multiple diverse food industry segments. However, at this critical time the full impact on business and international trade must be fully understood and considered. We are concerned that the proposed FDA registration rules lack real world international business input and may inadvertently negatively impact international trade. If even a small percentage of imported foods are delayed or removed from international trade as a result of the regulation, the cost implications for restaurants could be immediate and dramatic.

While we have carefully evaluated the proposed rules, we are not yet confident that we fully understand the myriad of logistical implications of the new information gathering requirements proposed in these new rules. We are especially concerned with the potentially negative impact the new requirements may have on international trade of small food quantities, wine, internet sales and the massive trade across the Canadian and Mexican borders.

02N-0276 C64

Background

The Bioterrorism Act contains a provision requiring the Secretary to issue a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. The Bioterrorism Act defines foreign facilities as those that manufacture/process, pack, or hold food for export to the United States without further processing or packaging outside the United States before export. Information FDA proposes to require on the registration form includes the name and full address of the facility; emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address; all trade names the facility uses; general food product categories under Sec.170.3; and a certification statement that includes the name, title/position, and phone number (e-mail address and fax number if available) of the registrant.

Additionally, under the proposed rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under Sec. 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is solely a warehouse/holding facility, and approximate dates of operation if the facility's business is seasonal. Under the proposed rule, facilities would also be required to submit timely updates when any information on their registration forms changes, including cancellation of the registration on a separate form.

The registration requirement applies to "facilities" as that term is defined in the statute and further explained by the legislative history. Specifically, "facility" includes any factory, warehouse, or establishment that manufactures, processes, packs or holds food, but does not include farms, restaurants, other retail food establishments, certain nonprofit food establishments, or fishing vessels. 21 U.S.C. 9 415(b).

When FDA receives the registration, FDA is required to notify the registrant that the registration was received and to assign a registration number to each facility. The Agency is further required to compile and maintain an up-to-date list of facilities that are registered under Section 415. The list and registration documents are not subject to disclosure under the Freedom of Information Act, nor is any information derived from the list or registration documents to the extent that such derivative information would disclose the identity or location of a specific registered person. See 21 U.S.C. 9 415(a)(4).

The FDA should request only the minimum information necessary for oversight:

The information FDA is requiring on the form is too specific, and may go beyond what is mandated by the statute. The name and full address of the facility, emergency contact information, and trade names are indeed needed. However, further requirements will be hard to maintain and update leading to unnecessary technical violations of the Act and possible product detention. Because of the international scope of the proposal, the amount of information required or requested, translation and the need for timely information updates, the proposed regulation creates a real potential for the FDA registration database system to become totally clogged, resulting in adverse consequences for domestic commerce and international trade.

The FDA should limit data collection to only the name and full address of the facility, emergency contact information and trade names. Other information collection should be avoided unless there is a compelling need. The FDA should also provide full translation services for non-English speakers and the disabled as required under the American's with Disability Act.

The proposed means of registration should be expanded:

The Agency clearly has not fully considered the costs and difficulties electronic registration poses to small international suppliers in remote areas of the world. The statute did not prescribe a specific process by which FDA should implement the registration requirement for facilities; instead, it left the process and development phase to the Agency's discretion. Although primarily a logistical issue for the FDA to solve, we recommend that any process must allow for maximum flexibility to reflect the varied and complex nature of the international food industry. It is expected that registrations will be submitted from almost every area of the globe. Specifically, FDA should permit registrations to be filed with the Agency in almost any form to include: electronic, telephone, fax, mail or via paper. We expect that many in the international food industry will prefer electronic filing. However, small businesses in remote areas may not have the capability to perform electronic filing as envisioned by the FDA.

We do not feel that the FDA has developed a truly workable plan for two way communication with world wide international business interests, and in particular small businesses in remote regions. We don't believe that FDA intends to eliminate small businesses in developing countries from international food trade by not providing for a reasonable means of communication. However, the proposed system may do just that. Clearly, the communication section of this proposal needs to be expanded with a focus on not inadvertently eliminating or prohibiting trade from developing nations or remote areas of the world.

The electronic registration system must be tested and absolutely secure:

The reliability and security of the newly proposed electronic registration system will be critical to international trade and to the free flow of foods. A new vulnerable terrorist target must not be created by FDA inattention or inexperience in this area. The economic survival of many restaurants today depends upon a reliable and cost effective flow of food products from far flung international suppliers. We believe that the FDA has not fully considered the costs associated with any potential disruption of their newly developed electronic registration system. To the extent that FDA establishes an electronic registration system, the Agency must consider the need for absolute redundancy and state of the art methods to protect the system's integrity. The system must be easy to use, in every world language, safe and must incorporate multiple safeguards to prevent the system from being used fraudulently. Without multiple and overlapping safeguards and absolute redundancy, persons intent on disrupting the international food supply might be able to enter fraudulent facility information for a targeted company or completely stop world food trade.

The new electronic registration system must be totally reliable with alternatives in place:

It is expected that the FDA will develop an electronic registration system that will incorporate suitable safeguards for the system and still be easy to use. In that eventuality, registration numbers should be assigned to facilities promptly, an immediate confirmation number must be generated electronically, and a return letter with a registration number should be mailed as quickly as possible to those who choose to register through first class mail or other means. The FDA should permit multiple facilities that are owned by a common entity to register individually or centrally, through the entity of common ownership. It should not be assumed that all registrations will be submitted electronically. Adequate capacity must be created for alternative registrations in a timely manor.

The FDA estimate of cost burden appears to be low:

The estimate of the cost burden that FDA has documented seems to be consistently under what even our best industry estimate would be. The FDA appears to have underestimated the complexity of translation to all world languages, the registration process itself, the number of facilities that would be required to register, and the annual reporting burden on facilities and parent firms. For example, FDA makes the assumption that those individuals, who do not understand English and do not have internet access, can meet the specific requirements for registration in approximately 12 hours. We have undertaken the task as native English speakers with internet access and find that the task has taken us over 20 hours of staff time to read, comprehend, gather the necessary data and complete the form. That is ten times the FDA estimated time. We believe one could double the time for a non-English speaking, non-internet user attempting registration. How can one assume that non-English speaking individuals can meet the registration requirements in the time estimated by FDA, without FDA being

knowledgeable of these foreign facilities day to day operations? Many foreign facilities do not even have specific addresses, plant managers or advanced technology to communicate and rely solely on the simplest of methods to do business. Again, how can these types of facilities been included in FDA's estimates of the total numbers and burden of time needed. Based upon our clearly unscientific analysis we would estimate that the burden on international registrants would be at least double, and the time for domestic registrants should be increased by a factor of ten.

Many more facilities may need to be registered than FDA estimates:

We truly believe that the facilities needing to meet the registration requirement is at least double the estimated number provided by FDA. For instance, FDA in particular has underestimated the number of international transportation/shipping facilities, which would be required to register since they ultimately hold some food in transit. Some examples to consider are FedEx, UPS, every international airline and the United States Postal Service. These types of transit companies may not have the required information requested by FDA to properly register the various unknown food products they routinely transport.

The FDA should consider exemptions for small quantities of food:

The burden of registration for respondents can be minimized by FDA collecting only the information that is absolutely necessary, exempting small quantities of food shipped on common carriers, and facilitating registration by any means of effective communication. Additionally, we request that the FDA look to the specific exemptions granted by Congress. Congress was precise in providing an exemption from registration to restaurants. Although the proposed document discusses that restaurants are exempt from registration; unfortunately, the document continues to define when it is necessary for food facilities to register and provides an opportunity for the foreign facilities to designate a U.S. agent for registration. This language alone contradicts the exemption in many circumstances within the restaurant industry. The intention of Congress was to exempt restaurants. Language must be incorporated to clearly state that foreign facilities may designate a restaurant as a U.S. agent for registration. However, this ability in no way removes the blanket exemption for restaurants. Only those restaurant operators who accept designation as a U.S. agent for registration are required to comply. This would minimize the burden of collection of information placed upon the restaurant industry.

The FDA registration should be a one-time only process:

The registration process should be a one-time only process. The legislative history regarding registration clearly expresses the intent of Congress that facilities perform a one-time (rather than an annual) registration and that such registration should serve to fulfill the statutory registration requirement. See 148 Cong. Rec. at H2726. Accordingly, FDA's regulations should only require that facilities subject to the registration requirement submit a single, one-time registration.

The ability to use a set time of 6-12 months for compliance with "timely notification":

The statute was equally clear that the registrant must notify FDA "in a timely manner of changes" to the information contained in the registration. It would be expected that such changes would include changes in the facility's ownership or other significant changes in the products distributed, manufactured, handled or processed at the facility. Although no clear precedent exists for timely notification in the food context, FDA should look to existing drug regulations for guidance. Specifically, FDA drug listings must be updated every June or December if a new drug is manufactured or discontinued in the facility during the previous six months. See 21 C.F.R., Subpart C, e.g., 0 207.30. We believe that the established FDA rules for drugs should be used as a guide for food. A time component of six to twelve months for changes should be adequate in the food context, as well. Moreover, temporary changes in the general food categories held or processed at the facility should not require additional notification to FDA.

The FDA should allow trade associations, commodity groups or parent companies the ability to register for facilities within their organizations:

The FDA should allow companies the flexibility to submit registrations and updates for all the company facilities from a single corporate headquarters. Many small food suppliers may not have access to electronic registration systems on site. The FDA should consider the allowance of company headquarters, trade associations or commodity groups to register facilities on our members' behalf. Because each component member must identify their facilities for purposes of membership, third party inspections, financial audit or quality control, many companies and trade associations already have well developed databases throughout the United States and some foreign countries. Flexibility in the registration process is also needed because many larger companies have developed positions at their corporate headquarters that are responsible for the licensing and permitting required at the state and local levels. By providing the flexibility to manage the FDA registration process as appropriate for their company, the costs of compliance and the burdens on business will be diminished and compliance should increase.

In closing, the National Restaurant Association strongly believes that sharing information and expertise with all food industry partners is crucial to the food industry's preparedness for potential food-contamination events. While we have carefully evaluated the proposed rules, we are not yet confident that we fully understand the myriad of logistical implications of the new information gathering requirements and the impact on international food trade. We are especially concerned with trade from small businesses in developing countries and trade across the Canadian and Mexican borders.

If the federal government and food industry work together in order to ensure the safety of the food supply, deploying available resources effectively and efficiently is the critical first step. Adjusting the information collection requirements for food imports as we have suggested will enable FDA and industry to comply with Congressional directives without wasting or misdirecting scarce national resources. As such, The National Restaurant Association would like to offer our assistance in helping the FDA determine the true impact of these rules and develop appropriate alternatives.

Thank you for the opportunity to submit these comments. Please feel free to call our Health and Safety Regulatory Affairs Department with any questions you may have regarding this issue, at (202) 331-5900.

Sincerely,

Steven C. Anderson
President and Chief Executive Officer

Steven F. Grover
Vice President
Health and Safety Regulatory Affairs

Cc: Lee Culpepper, Senior Vice President of Government Affairs and Public Policy
Peter Kilgore, Senior Vice President & General Counsel
Mary Adolf, Chief Operating Officer, NRAEF
Allison Whitesides, Legislative Representative

1200 SEVENTEENTH STREET NW, WASHINGTON DC 20036-3097 202/331-5900 FAX: 202/973-3952

NATIONAL RESTAURANT ASSOCIATION®

Restaurant Industry Facts

Locations.....858,000
Employees..... 11.6 million
Restaurant-Industry Share
Of the Food Dollar ....46.1 Percent

2002 Industry Sales Projection: $408 billion

Did you know that...

- The restaurant industry is the cornerstone of the economy, career and employment opportunities and community involvement?
- In 2010, the restaurant industry will operate more than one million units with sales of $577 billion, representing over 53 percent of the food dollar?
- The restaurant industry employs 11.6 million people, making it the nation's largest employer outside of government?
- One-third of all adults in the United States have worked in the restaurant industry at some point in their lives?
- Eating & drinking places employ more minority managers than any other industry?
- Nine out of 10 tableservice-restaurant operators raise money for charities, or donate food or space?
- More than two-thirds of tableservice-restaurant operators consider tourists important to their business?

800-424-5156
www.restaurant.org

Health and Safety Regulatory Affairs
Fax Cover Sheet

To: Docket No. 02N-0276

Company: Dockets Management Branch

Fax Number: 301-827-6870

From: Christine Andrews, Manager Public Health and Safety

Phone Number: (202) 331-5985

Fax Number: (202) 973-3671

Date: 4-4-03

This fax is 8 **pages (including cover sheet).**

Comments: